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SUMMARY of SAFETY AND EFFECTIVENESS

The name of the device, Ocu-Flex-53 (ocufilcon B) Soft (Hydrophilic) Contact Lens is classified as a Class II device. It has been F.D.A. approved, see PMA P820051 and Amendments since March 7, 1984, and is indicated for use as a daily wear soft contact lens. Lens configurations include spherical, toric and aspherical for non-diseased eyes. The tinted version of the Ocu-Flex-53 (ocufilcon B) Soft (Hydrophilic) Contact Lens is substantially equivalent to that of the untinted version as demonstrated in this submission. Manufacturing and sterilization procedures have not been changed from the F.D.A. approved procedures already in place. The dye used in the tinted version, Reactive Blue 21, is F.D.A. approved for use with poly(hydroxyethyl methacrylate) copolymers. No technological differences between the predicate device, Ocu-Flex-53 (ocufilcon B) Soft (Hydrophilic) Contact Lens (untinted) and the Ocu-Flex-53 (ocufilcon B) Soft (Hydrophilic) Contact Lens (tinted) were found. For example, all of the physical properties, such as refractive index, light transmission, water content, linear swell and oxygen permeability, are virtually identical for the untinted lens and the tinted version of the predicate device. As shown in the supporting attachments, there are no adverse effects on the physical or optical parameters of the Ocu-Flex-53 tinted lenses.

Overall, all of the performance data verify the substantial equivalence for the tinted and untinted version of the same lens.

Signed Charles R. Vermette
Charles R. Vermette, President

Date 2/6/96

Physical and Optical Properties of Tinted Versus Untinted Lenses

Introduction

All physical, chemical and optical properties were determined at $25^{\circ}\text{C} \pm 1^{\circ}\text{C}$ except for oxygen transmissibility, which was measured at $35^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

Color and Light Transmission

Color Index Code: Reactive Blue 21. Light transmittance was measured at various wavelengths in the visible region, i.e., from 350 to 700 nm. The minimum tint, or Visint, showed a maximum transmittance of 97.2% and a minimum transmission of 82.59%. The same untinted lens showed a maximum transmission of 96.9% and a minimum transmission of 82.5%. Ocu-Flex-53 Lenses, tinted with the maximum intensity of dye, showed a maximum transmission of light of 91.2% and a minimum of 1.75%. See STS Final Report, Study No. GLP-1995-605, of 09/11/95 and STS Final Report, Study No. GLP-1995-324 of 06/08/95 for original data (Attachment 2).

These data suggest that low concentrations of Reactive Blue Dye 21, such as would be used in cosmetic tints, would have no adverse effect on light transmissibility but that the maximum intensity of dye should be avoided.

Refractive Index

The refractive index of Ocu-Flex-53 Tinted Lenses (maximum intensity) is 1.4052 with a standard deviation 0.0009. The untinted version of the same lens has a refractive index of 1.4041, which is within the reproducibility of the measurement. Consequently tinting of Ocu-Flex-53 Contact Lenses with Reactive Blue 21, even at the maximum intensity does not affect the refractive index, see Attachment 3.

Water Content

The average water content of ten (10) Ocu-Flex-53 Contact Lenses, Lot IR, is 52.93%w. After tinting with maximum concentration of dye the average water content of the same 10 lenses is 53.11%w. The increase of 0.34% is well within the tolerance specifications of $\pm 1.0\%w$. See Attachment 4.

Linear Swell

The average linear swell of ten (10) Ocu-Flex-53 Contact Lenses, Lot IR, is 34.41. After tinting the same 10 lenses showed a linear swell of 34.8 or an increase of about 1.0%, which is well within the tolerance specification. See Attachment 4.

Optical Properties

The optical properties of ten (10) untinted Ocu-Flex-53 lenses, lot IR, are considered to be excellent, except for Lens no. 1 which was rated only fair. After tinting the same ten (10) lenses were still rated excellent, except for lens #1, which was rated only fair before tinting. See Attachment 4. These results indicate the tinting with Reactive Dye 21 does not affect the excellent optical parameters of Ocu-Flex-53 Contact Lenses listed in Figure 3.

Oxygen Permeability at 35°C

Oxygen Permeabilities at 35°C were calculated from their respective transmissibilities that, in turn, were measured with the aid of a Rehder Development Polarographic Cell and a Schema Versatae Polarographic Amplifier. To minimize the number of uncontrolled variables the permeability of the untinted lenses first was established. The lenses were then tinted and the permeabilities determined again on the same lenses.

Attachment 5 illustrates quite clearly that tinting does not detract from the excellent transmissibility of Ocu-Flex-53 Lenses. For example the untinted Ocu-Flex-53 Lens showed an average transmissibility (DK/L), at 35°C, of 7.6, with a standard deviation of 0.69. After tinting the average transmissibility (DK/L), at 35°C, was 7.7 with a standard deviation of 0.74. Similarly the average permeability of the untinted lenses at 35°C was calculated to be 16.7, with a standard deviation of 2.19 while the same lenses after tinting had an average permeability (DK x 10⁻¹¹) at 35°C, of 16.8 with a standard deviation of 2.00.

Optical Parameters of Ocu-Flex-53 Tinted Lenses Figure 3

The optical parameters of Ocu-Flex-53 Tinted Lenses and their tolerances **are the same** as those specified for Ocu-Flex-53 untinted lenses, namely:

Refractive Power: +10.00 diopters to -10.00 diopters with a tolerance of ± 0.25 diopters. For powers with more than ± 10.00 diopters the tolerance is ± 0.50 diopters.

Cylinder Power: for less than 2.00 diopters the tolerance is ± 0.25 diopters. For more than 2.00 diopters the tolerance is ± 0.5 diopters.

Cylinder Axis: tolerance of $\pm 5^\circ$ as stated on label.

Base Curve: measured in dry state, tolerance $\pm 0.02\text{mm}$.

Diameter: within ± 0.15 mm of stated value on label.

Center Thickness: within ± 0.10 mm of thickness stated on label.

Physical Appearance: attractive.

Color: very light turquoise (visitint) to darker turquoise.

Surface Quality: there must be no defects such as scratches, chips or gouges.

Edges: free of defects.

Optical Quality: lenses must contain no bubbles, waves or foreign bodies, when viewed under 10X magnification, or greater, with an illuminated background.

In summary, tinting of Ocu-Flex-53 Contact Lenses with Reactive Blue 21 Dye has no adverse effects on either the physical or optical properties, even at relatively high intensities of color. It is noted, however, that at the maximum tint level, 181 μg per lens, light transmittance is greatly reduced at the longer and shorter wavelengths of the visible region. At low, or Visitint levels, however, there is essentially no reduction in light transmittance.